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UNITED STATES DISTRICT COURT**DISTRICT OF NEVADA**BARBARA HEINRICH and GREGORY
HEINRICH,

Plaintiffs

v.

ETHICON, INC.; ETHICON LLC; and
JOHNSON & JOHNSON,

Defendants

Case No.: 2:20-cv-00166-APG-VCF

**Order Granting in Part Motion to Exclude
Opinion of Vladimir Iakovlev****[ECF No. 48]**

This case was part of multidistrict litigation (MDL) assigned to the United States District Court for the Southern District of West Virginia concerning the use of transvaginal surgical mesh to treat stress urinary incontinence (SUI). Plaintiff Barbara Heinrich alleges that she suffered injuries after having the TVT-SECUR (TVT-S) product implanted. The TVT-S was designed and manufactured by defendants Johnson & Johnson and Ethicon, Inc. ECF No. 4. This case was recently remanded from the MDL court with several motions pending.

The defendants move to exclude the testimony of Dr. Vladimir Iakovlev regarding his differential diagnosis and his opinion on future symptoms and pain. The defendants first challenge Dr. Iakovlev's opinion that Heinrich's injuries were caused by the mesh by ruling out other potential causes. The defendants contend that he lacks qualifications to make that determination and that he failed to account for other possible causes, such as Heinrich's history of urinary tract infections prior to the implantation and her other surgeries. The defendants next challenge Dr. Iakovlev's opinion that Heinrich is likely to suffer future urinary complications. They contend he is a pathologist, not a clinician, and has never examined Heinrich so he lacks

1 qualifications and a reliable basis to form that opinion. They also argue Dr. Iakovlev's opinion is
2 not helpful to the jury because he merely identifies a risk of future injury without quantifying it.

3 The plaintiffs respond that Dr. Iakovlev is qualified by his education and experience,
4 including clinical consulting in which he examines pathology specimens, reviews the patient's
5 clinical information, and reaches conclusions about the cause of a patient's injuries. The
6 plaintiffs argue Dr. Iakovlev performed a proper differential diagnosis in his field of pathology,
7 where he ruled out any other pathological cause for the injuries, and they contend the defendants
8 have not identified any other pathological cause that he failed to rule out. And they contend he
9 based his opinion on the mesh implant's known effects on tissue. As to his opinion on future
10 injuries, the plaintiffs argue Dr. Iakovlev is qualified based on his experience and his review of
11 Heinrich's records.

12 The parties adopt Judge Goodwin's prior statement of the standard for reviewing motions
13 challenging expert testimony under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow*
14 *Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), so I do the same. See *Huskey v. Ethicon, Inc.*, 29 F.
15 Supp. 3d 691, 701-02 (S.D.W. Va. 2014); *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014
16 WL 3361923, at *1-3 (S.D.W. Va. July 8, 2014).

17 **A. Differential Diagnosis**

18 The defendants challenge the following opinion by Dr. Iakovlev:

19 On pathological examination, the excision specimens showed that the lesional
20 tissue was formed by the mesh. There was no other detectable pathological cause
21 for the complications. Therefore, both clinical and morphological findings
22 narrowed the differential diagnosis to the mesh.

23 ECF No. 48-2 at 39.

1 Dr. Iakovlev is an anatomical pathologist. “A pathologist is a clinician who provides
2 diagnoses for patient care based on the examination of specimens they receive and relevant
3 clinical information.” *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 712 (S.D.W. Va. 2014).
4 Dr. Iakovlev conducts “diagnostic examination of specimens surgically removed from human
5 patients,” and his “annual practice volume amounts to 3000-5000 cases.” ECF No. 61-1 at 2.
6 Additionally, he provides “clinical consultations to physicians at St. Michael’s Hospital, which
7 requires [him] to examine pathology specimens, review clinical information relating to the
8 patient, and reach conclusions about the cause of a patient’s injuries or illnesses.” *Id.* He has
9 “reviewed over 250 cases of explanted meshes, including approximately 170 transvaginal mesh
10 specimens.” *Id.* at 3. The defendants do not question his qualifications as a pathologist.

11 Instead, they contend that as a pathologist, he is not qualified to perform a differential
12 diagnosis in this case, and that in any event he failed to account for other possible causes of
13 Heinrich’s injuries, so his differential diagnosis should be excluded. But Dr. Iakovlev is
14 qualified as a pathologist to opine that there is no other pathological cause for Heinrich’s injuries
15 following a review of her medical records and examination of specimens of the mesh and her
16 tissue. ECF No. 48-2 at 34-39. He thus “based his opinions in large part on reliable pathology
17 methods. He reviewed clinical records, examined explanted specimens, considered possible
18 causes of pain, and came to a diagnostic conclusion.” *Eghnayem*, 57 F. Supp. 3d at 712. An
19 expert’s causation opinions will not be excluded “because he or she has failed to rule out every
20 possible alternative cause of a plaintiff’s illness.” *Westberry v. Gislaved Gummi AB*, 178 F.3d
21 257, 265 (4th Cir. 1999) (quotation omitted). To the extent there are other possible causes, that
22 goes to the weight of Dr. Iakovlev’s testimony, not its admissibility. I therefore deny this portion
23 of the defendants’ motion.

1 **B. Continued Risk of Pain and Symptoms**

2 The defendants challenge the following opinion by Dr. Iakovlev:

3 Based on my knowledge and experience, my review of the published literature
4 and my own research in the field of implantable meshes, my review of the clinical
5 records of Ms. Heinrich and examination of the specimen described above . . . [i]t
6 is my opinion to a reasonable degree of medical certainty that the residual tissue
7 damage and scarring caused by the TVT Secur mesh and the subsequent surgeries
8 continued and continue to pose a risk for de-novo urinary symptoms for Ms.
9 Heinrich.

10 ECF No. 48-2 at 40-41.


11 Dr. Iakovlev’s opinion about continued risk of urinary symptoms and pain is conclusory.
12 He does not explain how he reached that conclusion or on what he is basing it. He did not
13 examine or treat Heinrich. And he points to nothing in his own experience, case studies, or
14 medical literature to support this opinion. The plaintiffs do not, for example, point to where in
15 his report or deposition testimony he identifies studies or literature showing that women who
16 have mesh implantation with resulting tissue damage and scarring have a continued risk of
17 urinary symptoms. Nor do they identify where in his report or deposition testimony he describes
18 his own clinical experiences where women with mesh implantations and resulting complications
19 have a continued risk of urinary symptoms and pain.

20 The plaintiffs therefore have not met their burden of showing that this particular opinion
21 is based on sufficient facts or data, is the product of reliable principles and methods, and that Dr.
22 Iakovlev reliably applied the principles and methods to the facts of this case. *See United States v.*
23 *87.98 Acres of Land More or Less in the Cty. of Merced*, 530 F.3d 899, 904 (9th Cir. 2008)
 (stating that the proponent of expert testimony “has the burden to establish its admissibility”);
 Fed. R. Evid. 702. Consequently, I grant this portion of the defendants’ motion and this opinion
 is excluded.

1 **C. Conclusion**

2 I THEREFORE ORDER that the defendants' motion to exclude the testimony of
3 Vladimir Iakovlev (**ECF No. 48**) is **GRANTED in part**. Dr. Iakovlev's opinion regarding a
4 continued risk of pain or urinary symptoms is excluded. The motion is denied regarding
5 Iakovlev's differential diagnosis opinion.

6 DATED this 17th day of April, 2020.

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10 ANDREW P. GORDON
11 UNITED STATES DISTRICT JUDGE
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